

## **METHOD AND APPARATUS FOR MEDICAL DEVICE FOR ASPIRATION OF THROMBOEMBOLIC DEBRIS**

### CROSS REFERENCE TO RELATED APPLICATIONS

- 5        This application claims the benefit of U.S. Provisional Patent Application  
Serial No. 60/190,513, filed March 15, 2000.

### **BACKGROUND OF INVENTION**

#### Field of Invention:

- 10        This invention relates to an apparatus and method for collecting blood clots,  
pieces of plaque and other material that may be accidentally dislodged during  
interventional procedures in the human vasculature such as arterial and venous  
angioplasty and stent placement. The invention utilizes a chamber that collects the  
blood from one sheath or catheter through an aspirating force where the blood can be  
15        filtered with removal of thromboembolic debris. The blood can then be recirculated  
back into the bloodstream through a second access.

#### Background Information:

- 20        It is common practice today to open occluded (i.e. blocked) or stenotic (i.e.  
narrowed) blood vessels by inserting a guidewire and then a catheter carrying a  
balloon shaped distal end and inflating the balloon, which exerts radial force, to press  
the stenosis outward against the wall of the vessel. This procedure is called balloon  
angioplasty. Frequently, an implantable metallic stent will be used additionally to  
provide greater radial strength and longer-term patency.

- 25        In order to help deliver the balloon catheters and the stent devices, special  
guiding catheters or sheaths are used. These guide catheters or sheaths are placed  
away (or upstream) from the targeted lesion. A guidewire will be advanced past the  
lesion, allowing the subsequent balloon catheters and stents to be advanced through  
the guiding catheter or sheath to the target lesion.

- 30        During balloon angioplasty and stent placement of the stenotic lesion, there is  
the risk of dislodging fragments of plaque, thrombus (blood clots) or other material. If

the lesion involves arterial circulation, then the particles could flow into smaller vessels in the brain, other organs or extremities resulting in disastrous complications. Likewise, if the lesions involve the venous circulation, then the thromboemboli could flow into the heart and lung possibly resulting in the demise of the patient.

5           It is the primary purpose of the present invention to provide such a protection. The device can be easily and remotely attached to catheters and sheaths ends. By initiating the device, slow and continuous aspiration will started. Blood will be drawn from the one vessel, filtered and then recirculated into the other vessel. This will allow effective trapping and removal of thromboembolic material.

10           The device could be attached to the proximal end of special guiding catheters that have a soft occluding balloon used to occlude flow into the vessel. Distal protection could also be provided by the insertion of a small balloon catheter in important branch vessels or past the lesion. Likewise, it can be attached to regular sheath or guiding catheter and provide needed aspiration during key parts of the case.

15           Benefits of the current invention include low speed rotating paddles or wheels which minimize trauma to individual blood cells which otherwise leads to hemolysis and potential problems such as rhabdomyolysis. Also, since it is a closed loop, there will be little if any blood loss.

20           The invention will have tremendous benefit in such procedures as carotid artery angioplasty and stent placement, where the incoming loop is attached to the guiding catheter or sheath in the artery and the outgoing system is attached to the venous sheath.

25           The invention will also have benefit in any procedure with the risk of thromboembolic debris such as other peripheral interventions as well as venous cases.

#### Description of Prior Art

30           There have been various devices and equipment to deal with stenotic lesions. As described, angioplasty and stents have been used to radially expand the lesion into the wall of the vessel. But these instruments can accidentally dislodge plaque and thrombus. Atherectomy devices are used to cut the plaque but have poor clinical results in actually treating the lesion and do not effectively trap thromboemboli.

Various patents have recently addressed the subject with the use of balloons or straining devices. However, their designs do not effectively trap particles or are too traumatic in crossing high grade stenoses. This invention provides these capabilities in addition to being attached simply to existing conventional guide catheters and sheaths.

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#### BRIEF DESCRIPTION OF THE DRAWINGS

A full understanding of the invention can be gained from the following description when read in conjunction with accompanying drawings in which:

Figure 1 is a longitudinal cross sectional view through a vessel such as a carotid artery showing the common carotid artery and the branches of the internal and external carotid arteries. Shown is the end of a guide catheter with a balloon near the distal tip. The inflated balloon is opposed to the vessel wall, helping to prevent thromboemboli from being sent downstream and into the cranial circulation. Also shown is a guidewire crossing the lesion. Over this guidewire, balloon catheters and devices to deliver and deploy the stent will be used.

Figure 2 is a longitudinal cross sectional view as shown in Figure 1 with the addition of second balloon catheter advanced and placed in the external carotid artery.

Figure 3 is a longitudinal cross sectional view as shown in Figure 1 with the addition of second balloon catheter advanced and placed in the internal carotid artery past the lesion in the artery.

Figure 4 is a longitudinal cross sectional view as shown in Figure 1 without the distal balloon segment.

Figure 5 is a top-down view of the device attached to "Y-adaptors" which are attached to the proximal ends of two guide catheters and/or vascular sheaths. The guide catheters and sheaths are inserted via the groin into the common femoral artery and vein.

Figure 6 is a top-down cross sectional view of the aspiration device with the ends attached through "Y-adaptors" which are connected to arterial and venous sheaths or guide catheters.

Figure 7 is a cross-sectional lateral view of the aspiration device.

Figure 8 is a cross-sectional side view of an alternate embodiment.

Figure 9 is a cross-sectional top view of the alternate embodiment.

### DESCRIPTION OF PREFERRED EMBODIMENTS

As shown in FIGS 1 -7, after a guidewire (1) is inserted into a blood vessel  
5 narrowed by a stenosis (2), a guiding catheter or long vascular sheath (3) is coaxially  
advanced proximal to the targeted lesion (2). In the present case, the distal end of the  
guiding catheter is located in the common carotid artery (4) and the targeted lesion (2)  
is located in the origin of the internal carotid artery (5). In this case, a special guiding  
catheter (3) is shown with a soft, expansible balloon (6) located near the distal tip (7).  
10 When the balloon (6) is inflated, the balloon will oppose against the vessel wall (8).  
This guiding catheter will have the balloon inflated during key parts of the case  
helping to prevent distal emboli from flowing downstream. The inflated balloon will  
also help provide increased aspiration force. When aspiration is begun, blood and  
thromboembolic debris from the treated lesion (2) will be drawn into through the  
15 main lumen (9) of the guiding catheter or long vascular sheath (3).

Minor modifications to the procedure would include the additional passage of  
a small balloon catheter (10) into a branch artery, such as the external carotid artery  
(11) in this case. Likewise, a separate, coaxial balloon guidewire/catheter (12) could  
be used through the guiding catheter (3) and when inflated, complete blockage will be  
20 obtained both proximal and distal to the lesion (13). Finally, aspiration through main  
lumen (9) could be obtained through conventional guiding catheters and vascular  
sheaths (14) without the occluding balloon segment.

Aspirated blood and thromboembolic debris is drawn through the main lumen  
(9), the proximal end of the guiding catheter (15), which exits the patient, and through  
25 and the luer lock insertions (16). A "Y-adaptor" (17) attaches to the main lumen (9)  
through this luer lock (16). The "Y-adaptor" (17) is composed of a sidearm port (18)  
and a main channel (19), through which runs guidewires and other coaxial systems.  
The sidearm (18) of the "Y-adaptor" (17) is attached to a three-way stopcock (20).  
The inflow tubing (21) of the present invention is attached through this three-way  
30 stopcock (20).

The inflow tubing (21) inserts into the proximal end (22) of the invention chamber (23). There is a one-way valve (24) to prevent backflow of blood and thromboembolic debris. Two-to-four paddles (25) rotate within the invention chamber (23) upon a central axis (26). There are micropores (27) within the paddles (25) to prevent hemolysis. The blood and thromboembolic debris first pass through an anterior wall (28), through the paddle section (25) and then pass through a posterior floor (29) at the base of the chamber. The posterior floor (29) has pores (30) of varying size to serve as sieve, allowing blood to pass to the distal end (31) of the device, while capturing thromboembolic debris. Blood will pass through the distal one-way valve (32) and into the outflow tubing (33) where it is inserted on to the sidearm (34) of a "Y-adaptor" (35) which is attached to the venous sheath (36). Blood is then returned back into the circulation.

The central axis (26) rotates through a series of flywheels (37) which are rotated though a small engine (38). The engine (38) is powered by batteries or electrical source (39) located on the outside of the chamber. There is a small switch (40) to operate the device.

An alternate embodiment of the invention is shown in Figures 8 and 9. In this embodiment, the chamber 23' includes a spherical inner chamber 42. Within spherical chamber 42 are semicircular paddles 25'. The paddles 25' rotate on an axis 26' which is disposed generally perpendicular to the axis of the elongated chamber 23. The axis 26' extends beyond the chamber 23. As such, the fly wheels 37' and engine 38' are disposed outside of the chamber. An additional filter 41 may be disposed in the outflow tubing 33.

While specific embodiments of the invention have been described in detail, it will be appreciated by those skilled in the art that various modifications and alternatives to those details could be developed in light of the overall teachings of the disclosure. Accordingly, the particular arrangements disclosed are meant to be illustrative only and not limiting as to the scope of invention which is to be given the full breadth of the claims appended and any and all equivalents thereof.